October 17, 2025

Remi
℅ Jennifer Day
Regulatory Correspondent
Prime Path Medtech
1321 Upland Dr
Suite 6792
Houston, Texas 77043

Re: K251778
Trade/Device Name: Remi Custom Night Guard
Regulation Number: Unclassified
Regulation Name: Mouthguard, Over-The-Counter
Regulatory Class: Class II
Product Code: OBR, OCO
Dated: September 17, 2025
Received: September 17, 2025

Dear Jennifer Day:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251778

Device Name

Remi Custom Night Guard

Indications for Use *(Describe)*

The Remi Custom Night Guard is Indicated for protection of teeth and restorations against grinding and clenching, and as an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K251778

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92.

Submitter: GrindGuard Inc

Company Contact Person: Oscar Adelman

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Submission Correspondent: Jennifer Day, Regulatory Affairs Consultant

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Houston, TX 77043

Phone: 314-809-1818

Email: jday@primepathmedtech.com

Date Prepared: 9/16/2025

Proprietary Name: Remi Custom Night Guard

Common Name: Mouth Guard

Product Code: OBR, OCO

Device Classification: Unclassified

Primary Predicate Device: FBCC Night Guard (K221369)

Secondary Predicate Device: NTI Clench Guard (K211158)

Reference Device: Thermoforming Sheet Materials (K200125)

Device Description:

The Remi Night Guard is a mouth guard used as a barrier between teeth for nighttime teeth grinding by creating physical separation between upper and lower tooth surfaces preventing tooth damage caused by bruxism (e.g., grinding and clenching).

Indications for Use:

The Remi Custom Night Guard is Indicated for protection of teeth and restorations against grinding and clenching, and as an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.

510(k) Summary K251778

Comparison to Predicate Devices:

Table 1. Predicate Comparison

Specification	***Subject Device:*** *Remi Night Guard*	***Primary Predicate:*** *FBCC Night Guard*	***Secondary Predicate:*** *NTI Clench Guard*
510(k)	K251778	K221369	K211158
Product Code	OBR, OCO	OBR	OBR, MQC, OCO
Panel	Dental	Dental	Dental
Class	Unclassified	Unclassified	Unclassified
OTC or Rx	OTC	OTC	OTC & Rx
Anatomical Sites	Worn on maxillary or mandibular teeth	Worn on maxillary or mandibular teeth	Worn on maxillary teeth
Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Patient Removable?	Yes	Yes	Yes
Indication for Use	The Remi Custom Night Guard is Indicated for protection of teeth and restorations against grinding and clenching, and as an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.	The LIJIA Night Guard is indicated for protection of teeth and restorations against grinding and clenching.	1. As an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing; 2. Protection against bruxism or nighttime teeth grinding and reduce damage and the noise associated with bruxing and/or grinding.

Indications for Use:

The indication for use is aligned with the Primary Predicate and Secondary Predicate devices. Both devices are indicated for protection of teeth and restorations against grinding and clenching, and the Secondary Predicate is indicated for the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.

510(k) Summary K251778

Technological Features:

The Remi Night Guard uses the same mechanism of action as the Primary Predicate product and Secondary Predicate product. It is intended to be worn on the teeth to protect teeth and restorations against grinding and clenching. It also aids in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing. Remi Night Guards are manufactured using impressions and/or scans.

Non-Clinical Performance Testing

Durability testing was completed on these night guards.

An internal manufacturing validation was performed to test the dimensional accuracy of the manufacturing process for the Remi Night Guards.

Biocompatibility assessment testing was performed on the subject device in accordance with FDA Guidance Document, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and , ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", and ISO 7405 "Dentistry – Evaluation of biocompatibility of medical devices used in dentistry".

Clinical Performance Testing

No new clinical studies were required to establish substantial equivalence for the Remi Custom Night Guard.

Conclusion

Based on comparison of indications for use, user population (adults 18 years and older), mechanical and technological features, the Remi Night Guard is substantially equivalent to the Primary Predicate device (FBCC Night Guard, K221369) and the Secondary Predicate device (NTI Clench Guard, K211158).